

**REMARKS**

Reconsideration is requested.

Claims 13, 14, 17, 36 and 37 have been canceled, without prejudice. Claims 1-12, 15-35 and 38-40 are pending. Claims 31-35 have been withdrawn from consideration. Support for the amendments may be found throughout the specification. The claims have been amended without prejudice. No new matter has been added.

The Section 112, first paragraph "written description", rejection of claims 1, 2, 4-6, 8-30 and 38-40 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following comments.

One of ordinary skill in the art will appreciate that the applicants were in possession of the claimed invention at the time the application was filed.

The position 204 of the claims is definite and will be appreciated by one of ordinary skill. As disclosed on page 23, lines 1-8 of the specification, for example, a consensus numbering of codons has been used throughout the present patent application as filed, as described by Stuyver et al., 2001 (a copy of which was submitted with the Information Disclosure Statement of September 17, 2007). By this consensus numbering of codons this numbering is independent from the HBV genotype as has been exemplified in Table 1, on page 8 of the present patent application. The proposed numbering of the polymerase of HBV's starts with the highly conserved EDWGPCDEHG motif making the total length of the HBV reverse transcriptase/polymerase (rt domain) 344 amino acids long and genotype independent (see page 753, second column of the Stuyver article). This is a far more convenient

system than the system used before as will be clear from table 1 and recognized by those of ordinary skill in the art.

Withdrawal of the Section 112, first paragraph "written description", rejection is requested.

The Section 112, second paragraph, rejections of claims 1, 2, 4-30 and 38-40 is obviated by the above amendments. Support for the revisions to claim 7 may be found, for example, in Figure 2 of the specification. The Examiner's assertions regarding the use of the open transition term "comprising" are unfounded. One of ordinary skill in the art will appreciate, for the reasons noted above and based on the art of record, for example, the metes and bounds of the claimed invention. Withdrawal of the Section 112, second paragraph, rejections is requested.

The Section 102 rejection of claim 14 over Allen (Hepatology, 1998; 27:1670-1677) is moot in view of the above.

The Section 102 rejection of claim 18 over Allen is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

The Examiner's interpretation of claim 18 appears to not include the requirement to infer, from the nucleic acid sequence obtained in step (ii), the presence of the serine encoding codon .... "and, therefrom, said resistance to lamivudine or a combination of antiviral drugs comprising lamivudine of an HBV virus present in said biological sample." Claim 18 is novel over the article of Allen. The result of the claimed method is not described in the cited art such that the complete invention of the claim is not provided

by the cited art and the Section 102 rejection is not sustainable. Withdrawal of the Section 102 rejection is requested.

The Section 102 rejection of claims 21, 22, 25 and 26 over Zaijier (Journal of Clinical Microbiology, 1994, 32(9):2088-2091), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following comments.

Zaijier does not describe a diagnostic kit comprising a means for detecting an HBV polynucleic acid .....comprising a serine encoding codon at position 204.

In the Zaijier article four assays all applying in some way hybridization have been compared relating to sensitivity and specificity for the detection of HBV DNA. The cited art does not describe or suggest detection of any mutated HBV DNA, let alone a hybridization or other diagnostic kit suitable therefor.

Withdrawal of the Section 102 rejection is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested, The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required.

BOZDAYI  
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Amendment  
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Respectfully submitted,

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